K102808

Section 6 – 510(k) Summary

GC AMERICA INC.
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DEC 22 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information:

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Date Prepared: September 20, 2010

2. Device Name:

Proprietary Name: MI Varnish
Classification Name: Cavity Varnish (21CFR 872.3620)
Device Classification: Class II
Product Code: LBH

3. Predicate Devices:

Company	Device	K Number
A.R. Medical Inc. Pharmascience, Inc.	Duraflor	K961893
3M ESPE Dental Products	Vanish Varnish, 5% Sodium Fluoride White Varnish	K092141
GC Corporation	MI Paste Plus	K070854

4. Device description and Intended Use

MI Varnish is a fluoride varnish (5% sodium fluoride with CPP-ACP) which has a desensitizing action when applied to tooth surfaces. The application leaves a film of varnish on tooth and this may allow visual control and verification. MI Varnish is packed in unit dose and can be applied on teeth with a disposable brush.

The applicant device, MI Varnish is substantially equivalent to Duraflor and Vanish Varnish in intended use. Both devices are fluoride varnish as Cavity Varnish, and used for desensitizing action when applied to teeth.

The chemical composition is similar to the predicate devices (Duraflor and Vanish Varnish) with the exception of Recaldent (CPP-ACP). Recaldent is found in the predicate device MI Paste Plus.

5. Components and Mode of Action

The applicant device, MI Varnish is a paste formulation delivered in unit dose package and applied on the tooth surfaces with a disposable brush.

The chemical components of MI Varnish are similar to that of Duraflor. Components of MI Varnish that have been used in approved devices, MI Paste Plus (GC Corporation), Cavit G, K875133 (3M ESPE Dental products)/Vanish Varnish, K092141 (3M ESPE Dental products) are listed in the chemical formulation.

The mode of action of the applicant device is substantially equivalent to that of the predicate devices, Duraflor and Vanish Varnish.

6. Technological characteristics:
MI Varnish contains two new components that have not been used in dental varnish or predicate devices.

Hydrogenated rosin is a rosin derivative. It is made with hydrogenation treatment of usual rosin (CAS No. 8050-09-7). Rosin (Colophony) and other rosin derivatives are used as adhesive agents in FDA approved dental varnishes. These include Duraflor, Vanish Varnish, Enamel Pro Varnish, K062683 (Premier), and the other fluoride varnishes.

Rosin and hydrogenated rosin are structurally similar. Hydrogenated rosin retains the basic structure of rosin and has extra conjugated double bonds. The difference is reflected in appearance, color and physicochemical properties between rosin and derivatives, but not on toxicological properties.

Diethylene glycol monoethyl ether is a solvent of polyvinyl acetate. The compound is already being used in Japan as medical device in "Caviton EX" for temporary filling material. (The number: 221AABZX00131000 is approved by Health and Welfare Ministry in Japan)

7. Summary of Physical tests:

Summary of Performance Specifications

	pH	Consistency (mm)	Total fluoride (wt %)
MI Varnish	6.6	39(2)	2.4(0.1)
Duraflor	6.8	40(1)	2.2(0.1)
Vanish Varnish	6.4	26(1)	2.6(0.1)

According to GC Corporation R&D test methods.

As described above, the applicant device, MI Varnish is substantially equivalent to comparative devices, such as Duraflor and Vanish Varnish.

8. Description of Safety and Substantial Equivalence:

The applicant device is substantially equivalent to the predicate devices in its intended use.

Most of the chemical components in MI Varnish have been used in the predicate devices. MI Varnish contains two new components, however, one is a rosin derivative and another one is already being used as medical device in Japan. So, we believe that this fact well supports the compatibility of MI Varnish, and the safety of the applicant device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mark Heiss, DDS
Director –Academic and Regulatory Affairs
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

DEC 22 2010

Re: K102808
Trade/Device Name: MI Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: September 27, 2010
Received: September 28, 2010

Dear Dr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K102808 DEC 22 2010

Device Name: MI Varnish

Indications for Use:

MI Varnish is a fluoride varnish with Recaldent™ (CPP-ACP) that has a desensitizing action when applied to tooth surfaces. The application leaves a film of varnish on tooth and this may allow visual control and verification.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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